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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/004,118 | 10/30/2001 | Stanford Mark Moran | BMED-004/01US | 8022 |

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EXAMINER

ANDRES, JANET L

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 06/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

10/004,118

Applicant(s)

MORAN, STANFORD MARK

Examiner

Janet L. Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 31 March 2003.

2a) ☐ This action is FINAL.

2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-64 is/are pending in the application.

4a) Of the above claim(s) 1-54 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 55-64 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,7.

4) ☐ Interview Summary (PTO-413) Paper No(s) _____.

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II in Paper No. 6 is acknowledged. It is noted that the devices of Group II were mistakenly described as comprising interferon, when they are in fact drawn to devices for the delivery of interferon. However, the Groups are unaltered by this error and the rationale for the restriction is unaltered, because the devices also have other uses, such as the treatment of diabetes. Thus the restriction requirement is still deemed proper. Claims 1-64 are pending in this application. Claims 1-54 are withdrawn from consideration as being drawn to a non-elected invention. The restriction requirement of paper no. 5 is made final.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 55-64 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 079 405 A1, Corless et al., published 1983, and U.S. patent 5429602, Hauser, 1995.

Corless et al. teaches an infusion system comprising a controller that controls two pumps, one used for insulin and one for dextrose, on p. 9, line 39 and p. 10, lines 1-6. The pump rates can be altered; see p. 10, lines 29-39. Thus, Corless et al. teaches a system comprising two long-term delivery devices that can deliver drugs at constant rates, and those rates can be set to be different, anticipating the limitations of claim 55. This system could also be used to deliver the

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same drug at different rates. That Corless et al. teaches the delivery of two compounds does not change the nature of the device itself. Since the rates can be changes, the system taught by Corless et al. also anticipates the limitations of claim 56. The instructions of claim 57 constitute and intended use and do not alter the nature of the device itself; thus this claim is also anticipated by Corless et al. While claims 58, 59, and 62-64 specify that the drug be an interferon, the device of claim 55 is "a kit useful for the delivery" of a drug and the nature of the drug to be delivered does not, as is stated above, change the nature of the device itself. The device taught by Corless et al. could also be used to deliver interferon and thus it meets the limitations of these claims. The diseases to be treated, specified in claims 60-64, are similarly an intended use of the device and do not change the nature of the device itself.

Hauser also teaches an infusion pump system that comprises two pumps. See column 2, lines 14-45. The infusion rates are separately programmable; see column 7, lines 17-38. Thus, for the reasons set forth for Corless et al. above, Hauser anticipates the limitations of claims 55-64.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

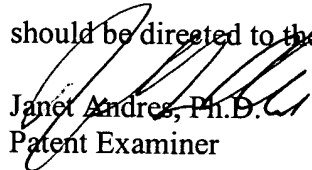
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

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Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Janet Andres, Ph.D.
Patent Examiner

June 11, 2003